K014155

510(k) Summary

MAR 1 8 2002

510(k) Number:
Contact Person: Ann Waterhouse, Regulatory Affairs Specialist
Date Prepared: December 13, 2001

Trade/Proprietary Name: Modified Arthrex Opening Wedge Osteotomy System
Regulation Number: 888.3030
Product Code: HRS
Classification Name: Plate, fixation, bone,

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Intended Use:

The Arthrex Modified Osteotomy System, designed for Opening Wedge Distal Tibial, Distal Femoral, Proximal Tibial Osteotomies, and High Tibial Closing Osteotomies, is used in conjunction with bone screws to provide fixation following surgery. Specifically for use in treatment of non-union, malunion, and fractures of proximal tibia, distal femur, and distal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures. Specially sloped plates can be used in cases when a tibial slope adjustment is needed. This system consists of plates and screws that join together to correct abnormalities or trauma related injuries. It is intended to be used with adequate post-operative immobilization.

Description:

The Arthrex Modified Osteotomy System consists of plates and screws that join together to correct abnormalities or trauma related injuries. Different sizes and configurations of the Modified Osteotomy System are available to address patient needs. The plates are configured to provide as much support as possible. The plates and screws are manufactured from stainless steel and are sold non-sterile.

Substantial Equivalence:

The Arthrex Modified Osteotomy System is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Modified Osteotomy System and predicate devices do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2002

Ms. Ann Waterhouse
Regulatory Affairs Specialist
Arthrex, Incorporated
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K014155
Trade Name: Modified Osteotomy System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Date: December 17, 2001
Received: December 19, 2001

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

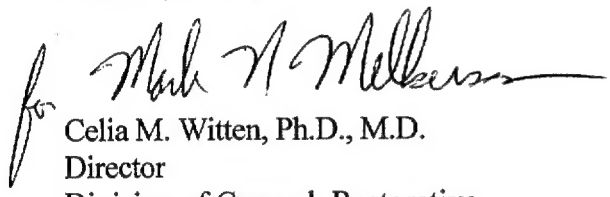
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **Arthrex Modified Osteotomy System**

Indications for Use:

The Arthrex Modified Osteotomy System, designed for Opening Wedge Distal Tibial, Distal Femoral, Proximal Tibial osteotomies, and High Tibial Closing Osteotomies, is used in conjunction with bone screws to provide fixation following surgery. Specifically for use in treatment of non-union, malunion, and fractures of proximal tibia, distal femur, and distal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures. Specially sloped plates can be used in cases when a tibial slope adjustment is needed. This system consists of plates and screws which join together to correct abnormalities or trauma related injuries. It is intended to be used with adequate post-operative immobilization.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014155

(Option Format 3-10-98)